

of a sample of said fluid with (1) a specific antibody for the free testosterone, and (2) a labeled analog of testosterone which is radioiodinated 6-hydroxy-testosterone-19-carboxymethyl ether histamine that binds to said antibody and has affinity for the endogenous binders lower than that of testosterone for said endogenous binders, (b) maintaining said mixture to permit said labeled derivative to compete with the free testosterone for binding with the antibody, (c) measuring the amount of said labeled analog that has, or has not, become bound to the antibody, and (d) determining the concentration of the free testosterone from said measurement, wherein the improvement comprises including in the mixture an amount of a blocking agent which is sulfobromophthalein to inhibit the binding of said labeled analog to the endogenous binders without displacing testosterone bound to said endogenous binders.

REMARKS

Reconsideration is requested in view of the foregoing amendment and the following remarks.

The objection maintained in paragraph 5 of the Office Action has previously been held in abeyance pending allowance. Applicant requests that his holding be continued.

The claim has been amended to eliminate the alleged new matter, Paragraph 11, second subparagraph, and paragraph 12 of the Office Action. The revised claim also resolves the point raised in paragraph 11, first subparagraph regarding alleged lack of

proper antecedent basis. The rejections under 35 USC 112 first paragraph and under 35 USC 112, second paragraph as stated in the Office Action, paragraphs 12 and 13, should be withdrawn.

The Examiner, beginning at the bottom of page 3 and continuing to the top of page 5, and reiterated in the rejection based on the Lost Interference Count, Paragraph 13, summarizes much of the prior history of this series of patent applications. However, the Examiner has not fully taken into account all of the facts and circumstances which bear on the patentability of claim 56.

Interference No. 103,933 did contain claims generic to the instant claim 56 in the sense that the practice of claim 56 would infringe applicants claim 1, for example, involved in the Interference (had the claim issued). Applicants original claim 1 involved in the Interference was held to be unpatentable over prior art and the Interference was terminated for lack of common patentable subject. Original claims 2-27 were held to be unpatentable over the issue.

The Examiner is correct that certain individual elements of the method of claim 56 are found in one or more of the original claims 1 to 27. However, none of claims 1 to 27 claimed a method utilizing the specific combination of elements, viz.

(1)-testosterone

(2) radioiodinated-6-hydroxy testosterone 19 carboxymethyl ether histamine

- (3) an antibody specific for testosterone
- (4) sulfobromophthalein blocking agent.

The method using the combination of (1), (2), (3) and (4) was

- (1) not claimed by this applicant (or any other party) in the Interference
- (2) was not rejected by the Board on prior art
- (3) Applicant could not have moved to add such a method claim to the Interference because none of the other parties had basis for such a claim as a review of their patent applications make clear.

The combination presented in claim 56 is clearly

- (1) a different invention,
- (2) novel, and
- (3) unobvious over the prior art.

Consider the Specification at page 26 which discloses that in a testosterone assay using sulfobromophthalein as the blocking agent, this blocking agent is uniquely effective in inhibiting the binding of the analog tracer (iodinated 6-hydroxy-testosterone-19 carboxymethyl ether histamine, Specification, p. 25, first paragraph) to the endogenous binder (albumin) without displacing testosterone bound to albumin.

Note this is to be contrasted with the use of salicylate, 2, 4-dinitrophenol and ANS (8-anilino-1-naphthalenesulphoic acid) which result in the displacement of testosterone bound to albumin and increase the apparent free testosterone as measured by the method, an unsatisfactory result. Thus, the combination of (1) (2) (3) and (4) gives a result not obtainable by the overly broad claims involved in the Interference. Claim 56 is patentable over the prior art and is "patentably distinct" from the claims involved in the Interference. Claim 56 should be allowed. As stated in In re Zletz, 893 F.2d 319, 13 U.S.P.Q.2d 1320, 1322-1323 (Fed. Cir. 1989):

"A losing party to an interference is entitled to claim subject matter other than that of the interference count, provided the requirements of patentability are met, and subject to those constraints that flow from the adverse decision in the interference. Frilette, 436 F.2d at 499-500, 168 U.S.P.Q. at 370-371 [In re Frilette, 436 F.2d 496, 168 U.S.P.Q. 368 (CCPA 1991)."]

The rejection based on the Interference is unjustified and should be withdrawn.

The Notice of Allowance is requested.

If any additional extension of time and/or fee is required, the Commissioner is authorized to charge our Deposit Account No. 13-4892.

Respectfully submitted,



Joseph E. Müeth
Reg. No. 20,532

Date: December 6, 2002

225 South Lake Avenue
Eighth Floor
Pasadena, California 91101
Telephone: (626) 584-0396